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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/359,975	07/23/1999	DAVID B. WEINER	UPAP-0345	3521
34137	7590	06/16/2004	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 06/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary

Application No.

09/359,975

Applicant(s)

WEINER ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 58, 59, 63, 64, 115-125 and 141-165 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 58, 59, 63, 64, 115-125 and 141-165 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 July 1999 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on 3/5/04 has been entered.

Obviousness Type Double Patenting Rejections

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 58, 59, 63-64, 115-125 and 141-165 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-14, 18-56 and 69-75 of U.S. Patent No. 5,981,505. Although the conflicting claims are not identical, they are not patentably distinct from each other for

reasons of record in the previous Office Action. The rejection has been expanded to include new claims 158-165 as a result of applicants' amendment filed 3/5/04. The new claims 158-165 are generic to the species recited in the '505 patent and hence the claims of the '505 patent would anticipate the claimed invention.

Claims 58, 59, 63-64, 122-125 and 148-161 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2-24 and 30-32 of U.S. Patent No. 5,817,637. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record in the previous Office Action. The rejection has been expanded to include new claims 158-161 as a result of applicants' amendment. The new claims 158-161 are generic to the species recited in the '637 patent and hence the claims of the '637 patent would anticipate the claimed invention. It is noted that while the claims of the '637 patent recite methods of immunizing (or treating) an individual against a pathogen or treating an individual who has a hyperproliferative disease, said methods recite the same steps as the instant claims and, like the instant claims, result in the induction of antibodies against the target antigen.

Claims 148-154, 156-157 and 162, 164-165 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. Patent No. 5,830,876. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record in the

previous Office Action. The rejection has been expanded to include new claims 162-165 as a result of applicants' amendment. The new claims 162 and 164-165 are generic to the species recited in the '876 patent and hence the claims of the '876 patent would anticipate the claimed invention. It is noted that while the claims of the '876 patent recite methods of immunizing (or treating) an individual against a pathogen or treating an individual who has a hyperproliferative disease, said methods recite the same steps as the instant claims and, like the instant claims, result in the induction of antibodies against the target antigen.

Claims 148-154, 156-157, 162, 164-165 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-9 of U.S. Patent No. 5,593,972. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons of record in the previous Office Action. The rejection is expanded to include new claims 162 and 164-165 as a result of applicants' amendment. The new claims 162 and 164-165 are generic to the species recited in the '972 patent and hence the claims of the '972 patent would anticipate the claimed invention. It is noted that while the claims of the '972 patent recite methods of immunizing an individual against a pathogen or hyperproliferative disease, said methods recite the same steps as the instant claims and, like the instant claims, result in the induction of antibodies against the target antigen.

Applicants, in the response filed 3/5/04, have not traversed the above Obviousness Type Double Patenting rejections but instead have indicated that they will file Terminal Disclaimers as appropriate upon indication of allowable subject matter.

35 USC 112, 1st Paragraph Rejections

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 58, 59, 63, 64, 115-125 and 141-165 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

This rejection is maintained for reasons of record in the previous Office Action and for reasons outlined below. The rejection is expanded to include new claims 158-165 as a result of applicants' amendment.

Applicants traverse this rejection by asserting that the specification teaches how to make and use compositions and practice methods for the production of antibodies and that the examiner has acknowledged that the specification enables the production of antibodies in an individual. Applicants assert that the examiner has improperly read limitations into the claims and then rejected the claims based upon said limitations. Applicants assert that the production of antibodies has other uses besides providing

active immunity in an individual. For example, applicants indicate that the antibodies so produced can be removed from the individual and used to provide passive immunity, in another individual, to a pathogen through administration of the antibodies. Applicants indicate that passive immunity methodologies are well known in the art. Applicants assert that none of the claims recite a method of inducing protective or therapeutic immunity in an individual and that the present enablement rejection is based upon limitations which are absent from the claims.

Applicant's arguments filed 3/5/04 have been fully considered but they are not persuasive.

As an initial matter, it is worth analyzing what exactly is being claimed in the instant application. The composition claims (58-59, 63-64, 122-125) are "pharmaceutical compositions" comprising DNA encoding an antigen from an intracellular pathogen such as HIV and therefore are intended to produce a therapeutic effect. The only disclosed use for the claimed pharmaceutical compositions is immunization (vaccination) of individuals against pathogen infection. The claimed pharmaceutical compositions must therefore be examined as therapeutic compositions. This is not reading a limitation into the claims since the claims explicitly recite "pharmaceutical compositions".

With regard to the method claims, the following is noted. The only disclosed uses for the claimed methods of introducing DNA molecules into cells of an individual (Claims 115-121, 141-147) involve induction of therapeutic effects in the context of immunization against pathogen infection or gene therapy for treatment of diseases such

as hyperproliferative cellular disorders. The only disclosed uses for methods of inducing antibodies against an antigen in an individual (Claims 148-165) likewise involve induction of therapeutic effects, i.e. immunization of individuals against pathogen infection. Since the specification must provide a disclosure sufficient to enable the skilled artisan to make and use the claimed invention, the specification must be examined with regard to what it teaches concerning how to make **and use** the claimed invention. Since the only disclosed use for the claimed methods is the elicitation of therapeutic benefits in an individual and since applicants have not enabled any therapeutic methods, the claims do not comply with the enablement requirement of 35 USC 112, 1st paragraph. This is not reading limitations into the claims, but only examining the application to determine whether it provides a disclosure sufficient to enable the skilled artisan to make and use the claimed invention without undue experimentation.

With regard to applicants' arguments that antibodies produced in an individual by the claimed method can be removed from the individual and used to generate passive immunity in another individual, it is noted that this is a method which is not being claimed. Applicants recite no claim involving methodology whereby antibodies to an antigen in an individual are induced, the antibodies are removed from the individual and are introduced into another individual so as to induce passive immunity to a pathogen in said individual. The only instantly disclosed uses for the claimed method of inducing antibodies against an antigen in an individual is for immunization of said individual

against infection by a pathogen from which the antigen was derived or treatment of cellular hyperproliferative diseases.

It is noted that applicants' do not indicate that the instant claims reading on generation of antibodies to an antigen exclude therapeutic or protective immunity in the individual. Indeed, as noted above, the instant specification only discloses therapeutic uses for the claimed methods. Since 35 USC 112, 1st enablement requires that the application enable the skilled artisan to practice the **full scope of the claimed invention**, applicants' arguments that the instant enablement rejection is reading non-existent limitations into the claims are incorrect.

Finally, applicants' citation of the decision in *CFMT Inc. v. Yieldup International Corp.* is not on point. In *CFMT Inc. v. Yieldup International Corp.*, the inventors claimed a general system to improve the cleaning process for semiconductor wafers and the specification provided enablement for the claimed invention. The Court held that the inventors did not have to enable the skilled artisan to make and use a "...perfected, commercially viable embodiment absent a claim limitation to the effect". Unlike the fact pattern in said case, the instant specification teaches that the uses of the claimed method of inducing antibodies in an individual to an antigen is for immunization (or treatment) of the individual against a pathogen or disease. The specification must teach the skilled artisan how to make and use the claimed invention without undue experimentation. If the only disclosed uses for the claimed invention are not enabled, then the claimed invention cannot be considered enabled.

It is noted that claims 115-121 and 141-147 read on a method of introducing DNA molecules into cells of an individual. The specification indicates that said method can be used for generation of immune responses (immunization) against a pathogen or gene therapy for treatment of disease. While the previous Office Action included an *In re Wands* Factor analysis based upon the claims reading on a method of introducing DNA with the intended purpose of providing immunization against pathogens, said Office Action did not provide a *Wands* Factor analysis for the lack of enablement based upon the claims reading on a method of introducing DNA into cells in an individual for the purpose of providing gene therapy for a given disease. The following is a *Wands* Factor analysis based upon the claims reading on introducing DNA molecules into cells in an individual for the purpose of gene therapy.

1) Unpredictability of the art. The gene therapy at the time of applicants' invention was (and remains today) extremely unpredictable. As noted by W. French Anderson in 1998 (Nature, Vol. 392, 1998, pp. 25-30), no definitive success in any gene therapy method had been demonstrated. The unpredictability in gene therapy is manifested in almost every aspect of gene therapy. The main issues involve gene delivery to the appropriate target cells and tissue and unpredictable and transient gene expression in the target cells or tissue. With regard to use of naked DNA in gene therapy, serious disadvantages include very short duration of expression of the transgene, inefficient transfection in vivo and ex vivo and retargeting transfection can be very difficult (For reviews of the unpredictability of gene therapy, see Verma et al., Nature, 1997, Vol.

389, pp. 239-242; Kmiec, 1999, American Scientist, Vol. 87, pp. 240-247); Mountain, TIBTECH, 2000, Vol. 18, pp. 119-128; Juengst, BMJ, 2003, Vol. 326, pp. 1410-1411).

2) State of the art. The gene therapy art at the time of applicants' invention was nil.

3) Scope of the invention. The scope of the invention must be considered broad. The claims read on a method of introducing any DNA molecules into any cells in an individual. The specification indicates that the DNA can be any DNA encoding any product usable in gene therapy for treatment of any disease in an individual.

4) Amount of guidance provided. Applicants provide no guidance sufficient to enable the skilled artisan to overcome the art recognized hurdles to successful practicing of gene therapy for any specific disease.

5) Nature of the invention. The invention involves the use of gene therapy techniques involving the delivery of DNA molecules to target cells for the purpose of treatment of disease.

6) Level of skill in the art. The level of skill in the art is high; however, given the unpredictability of the art, the lack of guidance provided by applicants, the broad scope of the claims and the poorly developed state of the art, it must be considered that the skilled artisan would have had to have conducted essentially trial and error experimentation in order to attempt to practice the claimed invention.

Given the above analysis of the factors which the courts have determined are essential for determining whether a claimed invention is enabled, it must be concluded

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that the skilled artisan would have had to have conducted undue and excessive experimentation in order to practice the claimed invention.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo
June 14, 2004



DAVID GUZO
PRIMARY EXAMINER